IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA	**:**	**CRIMINAL NO. 22-_____**
v.		**DATE FILED: _____**
MITCHELL SPIVACK	**:**	**VIOLATION:**
	:	**18 U.S.C. § 371 (conspiracy to**
	:	**defraud the United States – 1 count)**
		Notice of forfeiture

I N F O R M A T I O N

COUNT ONE

THE UNITED STATES ATTORNEY CHARGES THAT:

At all times material to this information:

1. Defendant MITCHELL SPIVACK was a registered pharmacist in the Commonwealth of Pennsylvania. Since in or about 1987, defendant SPIVACK owned and operated Spivack, Inc., d/b/a Verree Pharmacy (hereinafter "Verree") located at 7960 Verree Road, Philadelphia, Pennsylvania. Defendant SPIVACK was registered with the Pennsylvania pharmacy licensing board as Verree's pharmacist in charge. Defendant SPIVACK and his three coconspirator employees, who are known to the United States Attorney, had keys to Verree and the combination to the safe that contained cash and controlled substances.

2. Verree was a Pennsylvania corporation incorporated by defendant MITCHELL SPIVACK on or about June 22, 1987. Verree was a small, neighborhood pharmacy that was open for business seven days a week. Verree was registered with the Drug Enforcement Administration ("DEA") to purchase and dispense Schedule II-V controlled substances. Verree

submitted claims for reimbursement to health care benefit programs, including, Medicare Part D, for drugs that it purportedly dispensed using a national provider identifier (NPI) that was 1821198573.

Health Care Benefit Programs

3. Title 18, United States Code, Section 24(b) defined the term "health care benefit program" as any public or private plan affecting commerce, under which any medical benefit, item, or service is provided to any individual, and includes any individual or entity who is providing a medical benefit, item, or service for which payment may be made under the plan or contract.

4. Medicare was a "health care benefit program," as defined by Title 18, United States Code, Section 24(b). Medicare was a federal health insurance program administered by the Centers for Medicare and Medicaid Services (hereinafter, "CMS"), an agency of the United States Department of Health and Human Services. Medicare paid for reasonable and medically necessary medical services for people aged 65 and older and some persons under 65 with certain illnesses and/or disabilities.

5. Medicare Part D pertained to the subsidized payment of prescription drugs through the Medicare Modernization Act. Medicare Part D covered the cost of prescription drugs for Medicare beneficiaries.

6. Generally, pharmacies submitted claims to Medicare Part D plan sponsors for covered outpatient prescription drugs. A pharmacy's claims for these drugs were documented in a prescription drug event (PDE) record, which contained information provided by the pharmacy

about the drug dispensed, the beneficiary, the practitioner who prescribed the drug, and the drug's cost. Medicare relied on the accuracy of the information in the pharmacy claim when making payments.

7. Medicare Part D plan sponsors repeatedly certified their compliance with applicable federal laws, regulations, and CMS guidance and certified to the accuracy and truthfulness of the data in the PDE records as a condition of payment.

8. Medicare only covered drugs for a medically accepted indication, which was any use approved under the Food, Drug, and Cosmetic Act, or which was supported by one or more citations included or approved for inclusion in one of the listed compendia. PDEs submitted to Medicare that were not for a medically accepted indication do not contain accurate, complete, and truthful information about all data related to payment.

9. Pennsylvania Medicaid also paid for prescription drugs, but only when those drugs were "medically necessary." 55 Pa. Code §§ 1121.1, 1121.21.

The Controlled Substances Act and Pharmacist Duty

10. The Controlled Substances Act (CSA), Title 21, United States Code, Section 801 *et seq.*, and its regulations governed the distribution and dispensing of controlled substances. The CSA established strict guidelines "to ensure a sufficient supply for legitimate medical . . . purposes and to deter diversion of controlled substances to illegal purposes. The substances are regulated because of their potential for abuse and likelihood to cause dependence when abused and because of their serious and potentially unsafe nature if not used under proper circumstances." 75 Fed. Reg. 61613 (Oct. 6, 2010).

11. Federal legislation dictated how prescription drugs were categorized. Drugs could be placed in Schedules I through V based on, *inter alia*, their "potential for abuse" and whether they have "a currently accepted medical use in treatment." 21 U.S.C. § 812(b). For example, Schedule II controlled substances, which included dangerous and addictive opioids such as oxycodone, had a "high potential for abuse" that "may lead to severe psychological or physical dependence," but had "a currently accepted medical use in treatment." *Id.*

12. The CSA required those who distributed or dispensed controlled substances, including pharmacies that dispense controlled substances pursuant to a prescription, to obtain a registration from the DEA. Individuals or entities who had a registration were commonly referred to as "registrants."

13. The registration requirements for those who dispensed controlled substances were based on the statute's definition of a "dispenser," which was defined as "a practitioner who [] delivers a controlled substance to an *ultimate user*" "pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance." 21 U.S.C. § 802(10) (emphasis added). That definition included retail pharmacies that dispensed controlled substances directly to patients. When controlled substances were delivered without a valid prescription, the CSA defined this delivery as a "distribution."

14. For those entities such as retail pharmacies registered to dispense controlled substances, the CSA established strict limitations on when a controlled substance could be dispensed to the patient and ultimate user. It generally provided that, unless a non-pharmacy practitioner

dispensed directly or there was an emergency, Schedule II, III, and IV controlled substances could only be dispensed upon a "prescription." 21 U.S.C. § 829(a), (b).

15. A prescription was effective only if issued for a "legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04(a) (emphasis added).

16. In addition, the CSA's implementing regulations provided direction specifically for pharmacists by providing that "[a] prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his professional practice and either registered individually or employed in a registered pharmacy . . . ." 21 C.F.R. § 1306.06.

17. The CSA's implementing regulations explicitly warned pharmacists of the consequences of dispensing or distributing a controlled substance without satisfying these requirements. The regulations stated that the "responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a *corresponding responsibility* [for proper dispensing of controlled substances] rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. [§]829) and the person knowingly filling such a purported prescription . . . shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances." 21 C.F.R. § 1306.04(a) (emphasis added).

18. With respect to a pharmacist's "corresponding responsibility" to ensure proper dispensing and distribution of controlled substances, pharmacists had a legal duty to ensure

that prescriptions for controlled substances were legitimate before dispensing the controlled substance. The fact that a licensed physician actually or ostensibly prescribed a controlled substance did not obligate a pharmacist to fill that prescription. A reasonably prudent pharmacist was required to be familiar with suspicious activity or "red flags" indicating that the controlled substances prescribed were at risk for abuse or diversion. A pharmacist was likewise required to check the Pennsylvania Prescription Drug Monitoring Program ("PDMP") for suspicious prescriptions. The PDMP system was an electronic database that collected information on *all* filled controlled substance prescriptions. The pharmacist should have checked the PDMP to ensure that the patient was not obtaining controlled substances from more than one provider, was filling controlled substances at other pharmacies, and other "red flags" about the propriety of a controlled substance prescription.

19. A "red flag" could include anything about a controlled substance prescription that would cause the pharmacist to be concerned that the prescription was not medically necessary, or was not issued for a legitimate medical purpose by a registered prescriber in the usual course of professional practice. Some of the red flags for diversion that all pharmacists should have been familiar with included the following:

a) The prescriptions were for high dosage strengths of a controlled substance and/or for large quantities;

b) The prescriptions were part of a "cocktail" that usually included a prescription for an opioid, such as oxycodone, combined with a prescription for a benzodiazepine (anti-anxiety drug) such as alprazolam (also known by its brand name, Xanax), and possibly a muscle relaxant, such as carisoprodol (also known by its brand name, Soma) or cyclobenzaprine (also known by its brand name Flexeril). Such cocktail combinations were often sought by drug abusers and dealers because they produced an intensified "high." The combination of an

opioid, benzodiazepine, and muscle relaxant was typically referred to as a "Trinity cocktail," which was particularly dangerous and often resulted in overdose deaths;

c) Patients were willing to pay large sums of cash (or write checks or use credit cards) for controlled substances, even when the patients had insurance coverage available for the drugs;

d) Two or more controlled substance prescriptions were issued together at the same time for the same patient, which indicated duplicate therapy; for example, when a patient is issued oxycodone and OxyContin to treat the same condition in the same manner; and

e) The patient's address was a significant distance from the prescriber's address and/or the pharmacy's address.

20. When confronted with one or multiple red flags concerning a prescription for a controlled substance, a pharmacist was required by law to intervene and resolve the red flags to determine whether the prescription was for a legitimate purpose before filling the prescription. The pharmacist was required to document his or her findings for future use and reference.

21. There were some red flags that a pharmacist could not resolve by contacting the physician, obtaining a report from PDMP, or obtaining more information from the patient, such as those cases when the pharmacist had reason to believe that the physician was complicit in abuse or diversion of the controlled substance.

THE CONSPIRACY

22. From at least in or about January 2013 through in or about December 2019, in the Eastern District of Pennsylvania, defendant

MITCHELL SPIVACK

conspired, combined, and agreed with others known and unknown to the United States Attorney to commit certain offenses against the United States, that is:

a. to violate Title 18, United States Code, Section 1347, by knowingly and willfully executing a scheme to defraud the Medicare and Medicaid federal health benefit programs, and to obtain money and property of Medicare and Medicaid by means of false and fraudulent pretenses, representations, and promises, in connection with the delivery of and payment for health care benefits, items and services, by submitting and causing to be submitted fraudulent health care reimbursement claims; and

b. to violate Title 21, United States Code, Section 841(a) (1), by knowingly and intentionally distributing and dispensing, outside the usual course of professional practice and not for a legitimate medical purpose, a mixture and substance containing a detectable amount of oxycodone, a Schedule II controlled substance.

OBJECT OF THE CONSPIRACY

23. It was the object of the conspiracy for the defendant MITCHELL SPIVACK, and his conspirators, who are known and unknown to the United States Attorney, to unlawfully enrich themselves by (1) submitting fraudulent claims to Medicare and Medicaid for prescription drugs not dispensed; and (2) by filling medically unnecessary prescriptions for large quantities of oxycodone.

Manner and Means

The manner and means by which defendant MITCHELL SPIVACK and his coconspirators sought to accomplish the purpose of the conspiracy included, among other things, the following:

24. Verree maintained a computer system to acquire, track, dispense, and bill for prescription drugs dispensed by the pharmacy. Defendant MITCHELL SPIVACK and his coconspirators logged onto Verree's computers each morning with a login and password, and assign their initials to each activity taken. The pharmacy computer system recorded the initials of the pharmacist and technician who completed each activity taken. The computer system also maintained a patient profile record for each person who filled prescriptions at Verree. The profile included the patient's biographical information, insurance plan, each drug prescribed for the patient, name of the prescriber issuing the drug, the date on which each prescription was filled, and the number of refills permitted. The profile contained a comment section for the pharmacist and/or pharmacy technician to include relevant information, including but not limited to, prescribers' verification for controlled substances prescriptions and preferences.

25. Prescription drugs for which fraudulent claims would be submitted were designated in the comments section of the patients' profiles as "BBDF," which was an acronym for "Bill But Don't Fill." Defendant MITCHELL SPIVACK and his coconspirators caused entirely fraudulent claims to be submitted to health care benefit programs, including Medicare and Medicaid, based on "BBDF" designations for prescription drugs that were not dispensed.

26. Defendant MITCHELL SPIVACK and his coconspirators cultivated a reputation for Verree as an "easy fill" and "no questions asked" pharmacy for patients seeking to fill prescriptions for large quantities of oxycodone. At Verree, obviously altered prescriptions for oxycodone were filled without verifying the prescription with the issuing physician. Despite the fact that prescriptions had been altered, the oxycodone would be dispensed so long as a customer

had sufficient funds to pay for the drugs. Defendant SPIVACK and his coconspirators also filled prescriptions for wholesale quantities of high-dose oxycodone, despite the existence of "red flags" that indicated potential diversion of controlled substances, in which case the prescriptions should not be filled.

27. To avoid scrutiny by health care benefit programs that monitored the amount of oxycodone dispensed to beneficiaries, and to generate untraceable cash proceeds, defendant MITCHELL SPIVACK and his coconspirators typically required payment in cash for oxycodone prescriptions even when the customer produced proof of health insurance.

28. Defendant MITCHELL SPIVACK and his coconspirators also created a "club" wherein patients who paid a premium as "Narc Members" could expedite the filling of their high-dose oxycodone prescriptions with no questions asked.

Overt Acts

In furtherance of the conspiracy, and to effect its objects, defendant MITCHELL SPIVACK committed the following overt acts, among others, in the Eastern District of Pennsylvania:

1.-5. On or about the dates below, defendant MITCHELL SPIVACK submitted, or caused the submission of, fraudulent "BBDF" claims to Medicare for prescription drugs not dispensed, each a separate overt act:

Overt Act	Approx. Date	Drug
1	July 17, 2017	Symbicort
2	April 24, 2018	Proair HFA
3	May 24, 2018	Lyrica
4	August 2, 2018	Spiriva
5	February 1, 2019	Sertaline

6.-14. On or about the dates below, defendant MITCHELL SPIVACK knowingly and intentionally distributed and dispensed, outside the usual course of professional practice and not for a legitimate medical purpose, a mixture and substance containing a detectable amount of oxycodone, a Schedule II controlled substance, each a separate overt act:

Overt Act	Approx. Date	Drug	Quantity
6	June 21, 2017	oxycodone 30 mg.	360
7	July 1, 2017	oxycodone 30 mg.	240
8	November 13, 2017	OxyContin 80 mg oxycodone 20 mg	90 120
9	February 5, 2018	oxycodone 30 mg	240
10	February 26, 2018	oxycodone 30 mg	240
11	March 2, 2018	oxycodone 30 mg	240
12	July 24, 2018	oxycodone 30 mg	240
13	August 1, 2018	oxycodone 30 mg	240
14	August 20, 2018	oxycodone 30 mg	240

All in violation to Title 18, United States Code, Section 371.

NOTICE OF FORFEITURE

THE UNITED STATES ATTORNEY FURTHER CHARGES THAT:

1. As a result of the violation of Title 18, United States Code, Sections 371, charging conspiracy to violate Title 18, United States Code, Section 1347, and Title 21, United States Code, Section 841, as set forth in this information, defendant

MITCHELL SPIVACK

shall forfeit to the United States of America any property, real or personal, that constitutes or is derived, directly or indirectly, from gross proceeds traceable to the commission of such offense.

2. If any of the property subject to forfeiture, as a result of any act or omission of the defendant:

(a) cannot be located upon the exercise of due diligence;

(b) has been transferred or sold to, or deposited with, a third party;

(c) has been placed beyond the jurisdiction of the Court;

(d) has been substantially diminished in value; or

(e) has been commingled with other property which cannot be divided without difficulty;

it is the intent of the United States, pursuant to Title 18, United States Code, Section 982(b), incorporating Title 21, United States Code, Section 853(p), to seek forfeiture of any other

property of the defendant up to the value of the property subject to forfeiture.

All pursuant to Title 18, United States Code, Section 982(a)(7).

JENNIFER ARBITTIER WILLIAMS
UNITED STATES ATTORNEY

*No.*_ _ _ _ _ _ _ _ _ _

UNITED STATES DISTRICT COURT

Eastern District of Pennsylvania

Criminal Division

THE UNITED STATES OF AMERICA

vs.

MITCHELL SPIVACK

INFORMATION

18 U.S.C. § 371 (conspiracy to defraud the United States – 1 count)

A true bill.

_____
Foreman

Filed in open court this _____day,
Of _____A.D. 20_____

_____
Clerk

Bail, $_____